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ning of each regular issue of the PCT Gazette.

(54) Title: CONTROLLED RELEASE CGRP DELIVERY COMPOSITION FOR CARDIOVASCULAR AND RENAL INDICA-
TIONS

(57) Abstract: The present invention provides methods of treating heart failure and improving renal function, and/or preventing the advancement of heart failure into advanced stages, and methods of counteracting ischemia due to a myocardial infarction by providing improved methods of administering a therapeutically effective amount CGRP as a controlled release formulation. The therapies can be administered on an outpatient or inpatient basis and can further be used as maintenance therapies.

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INTERNATIONAL SEARCH REPORT

PCT/US2005/001225

| | | |
|---|--|--|
| A. CLASSIFICATION OF SUBJECT MATTER INV. A61K9/16 A61K9/00 A61K9/70 A61K38/22 | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61K | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched | | |
| Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ, CHEM ABS Data | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | EP 0 845 269 A (WO, WEIHAN) 3 June 1998 (1998-06-03) claims 1,8 page 2, line 11 - line 14 example 1 page 9, line 11 - page 11, line 25; table 8 | 1,15,16, 18,19, 24,31, 34,37, 40,43,47 |
| A | EP 0 765 659 A (SHISEIDO) 2 April 1997 (1997-04-02) claims 1-3,5,6 page 6, line 11 - line 19 column 7, line 14 - line 17 example 1 | 1-47 |
| -/-- | | |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. | | |
| <input checked="" type="checkbox"/> Patent family members are listed in annex. | | |
| * Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the International filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the International filing date but later than the priority date claimed *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *Z* document member of the same patent family | | |
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| Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 | | Authorized officer Ventura Amat, A |

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| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|-----------------------|
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | <p>EP 0 467 389 A (UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION) 22 January 1992 (1992-01-22) claims 1-4, 23-27 page 5, line 7 - line 17 page 5, line 40 - line 41 page 6, line 36 - line 39 page 6, line 57 - page 7, line 2 page 8, line 14 - line 20</p> | 1-47 |
| A | <p>EP 0 645 136 A (SHISEIDO) 29 March 1995 (1995-03-29) claims 1, 8, 10 page 9; examples 13, 14</p> | 1-47 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/001225

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 1-42,47 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

PCT/US2005/001225

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|---|---------------------|----------------------------|---------------------|
| EP 0845269 | A | 03-06-1998 | AT 214288 T | 15-03-2002 |
| | | | CN 1185974 A | 01-07-1998 |
| | | | DE 69710996 D1 | 18-04-2002 |
| | | | DE 69710996 T2 | 21-11-2002 |
| | | | JP 10245346 A | 14-09-1998 |
| | | | RU 2174843 C2 | 20-10-2001 |
| | | | US 5932244 A | 03-08-1999 |
| EP 0765659 | A | 02-04-1997 | JP 2909418 B2 | 23-06-1999 |
| | | | JP 9077657 A | 25-03-1997 |
| | | | US 5993855 A | 30-11-1999 |
| EP 0467389 | A | 22-01-1992 | AT 185269 T | 15-10-1999 |
| | | | AU 656897 B2 | 23-02-1995 |
| | | | AU 8046691 A | 23-01-1992 |
| | | | CA 2046830 A1 | 20-01-1992 |
| | | | CS 9102248 A3 | 18-03-1992 |
| | | | DE 69131677 D1 | 11-11-1999 |
| | | | DE 69131677 T2 | 24-02-2000 |
| | | | DK 467389 T3 | 28-02-2000 |
| | | | ES 2138584 T3 | 16-01-2000 |
| | | | FI 913455 A | 20-01-1992 |
| | | | GR 3032056 T3 | 31-03-2000 |
| | | | JP 5103838 A | 27-04-1993 |
| | | | MX 9100249 A1 | 28-02-1992 |
| | | | NO 912769 A | 20-01-1992 |
| | | | NZ 238951 A | 22-12-1994 |
| | | | PT 98397 A | 29-05-1992 |
| | | | ZA 9105584 A | 29-04-1992 |
| EP 0645136 | A | 29-03-1995 | AU 5538098 A | 23-04-1998 |
| | | | AU 687423 B2 | 26-02-1998 |
| | | | AU 7305594 A | 30-03-1995 |
| | | | CA 2132396 A1 | 21-03-1995 |
| | | | US 5637309 A | 10-06-1997 |